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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|------------------|
| 10/779,978   | 02/17/2004  | Peter M. Bonutti     | 782-A03-024                 | 9101             |
| 33771  | 7590        | 10/11/2011           |                             |                  |
| PAUL D. BIANCO<br>Fleit Gibbons Gutman Bongini & Bianco PL<br>21355 EAST DIXIE HIGHWAY<br>SUITE 115<br>MIAMI, FL 33180 |             |                      | EXAMINER<br>MASHACK, MARK F |                  |
|  |             |                      | ART UNIT                    | PAPER NUMBER     |
|  |             |                      | 3773                        |                  |
|  |             |                      | MAIL DATE                   | DELIVERY MODE    |
|  |             |                      | 10/11/2011                  | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/779,978

**Applicant(s)**

BONUTTI ET AL.

**Examiner**

MARK MASHACK

**Art Unit**

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2011.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-5, 7, 8, 10, 14, 24, 35-39, 44-46, 52, 53, 55, 57 and 59-63 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 2-5, 7, 8, 10, 14, 24, 35-39, 44-46, 52, 53, 55, 57 and 59-63 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/15/2011  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This office action is in response to a communication dated 7/13/2011. Claims 2-5, 7-8, 10, 14, 24, 35-39, 44-46, 52-53, 55, 57, 59-63 are pending.

#### *Response to Arguments*

1. Applicant's arguments filed 7/13/2011 have been fully considered but they are not persuasive. Applicant argues that "there is nothing in **Yoon** that states that element **512**, which **Yoon** identifies as a barrel, moves with respect to element **536**, which **Yoon** simply identifies as an outer member. If anything, barrel **512** is stationary and outer member **536** moves." Examiner disagrees. **Yoon** explicitly discloses in another embodiment "it is desirable that the grasping instrument **16** be longitudinally movable relative to barrel **12** such that the distal end of the grasping instrument can be retracted or drawn into the barrel for safety and protection" (Col 8, Lines 51-57). **Yoon** also depicts the outer member **536** being moved relative to the barrel **512** in the cited embodiment (Fig 28-29). Therefore, Examiner asserts that the barrel **512** would be capable of moving independently of the tubular member **536** and the intended use of apparatus claims does not distinguish it from the prior art. Applicant argues that "there is nothing in **Yoon**, inherent or otherwise, that teaches or suggests that anything that even arguably could be considered as a safety switch 'moves to the off position with movement of the elongate insulation sleeve to the second sleeve position' as recited in **claim 35**." Examiner disagrees. As discussed below, an on/off switch is inherent in the energy transmitter and the elongate sleeve can be moved, as discussed above.

Examiner asserts that the claim as written does not provide any causation and merely requires the two objects have to "move[s]... with" each other. Examiner asserts that the two actions can be performed "with" or at the same time as each other. Examiner recommends that the Applicant provide more causative language to define the relationship between the two actions.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claim 63** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed specification does not disclose of the "second actuator".

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claim 63** recites the limitation "the first actuator". There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 2-5, 7-8, 10, 14, 24, 35-39, 44-46, 59-63** rejected under 35 U.S.C. 102(b) as being anticipated by **Yoon (US 5,908,429)**.

**Regarding Claim 14, 24, 59-61 Yoon** discloses of a device comprising:

a first member **538** including a compressive element **550a**;

a second member **536** including a proximal and a distal end, the distal end having a gapped portion **560** with a second compression element **550b** being integrated into the gapped portion, wherein the tubular second member is movable along a linear path relative to the first member from a first position to a second position, and wherein the first compression element and the second compression element are capable of receiving a retainer therebetween (Col 21, Line 62, - Col 22, Line 16);

an energy source operably connected to the first compression element (Col 21, Lines 57-61 and Col 8, Lines 57-59); and

an elongated insulation sleeve **512** controllably positionable over the tubular second member (Col 8, Lines 44-47), the elongated sleeve further comprising a collar member (proximal collar as labeled **22** in Fig 1), capable of receiving an end portion of a

suture, wherein the insulation sleeve **512** is capable of insulating the suture attached to the collar member from energy from the energy source (Col 8, Lines 51-59).

**Regarding Claim 35**, the insulation sleeve is controllable positioned over the gapped portion and the sliding is independent of the tubular member and an on/off switch is inherent which also serves also a "safety switch" capable of preventing delivery of energy to the gapped portion of the tubular member when the insulation sleeve is in the second position. **Regarding Claim 36**, a retainer is capable of being received between the first and second compression elements. **Regarding Claims 37**, the actuating member **540** is capable of moving the tubular member from an open and a closed position. **Regarding Claims 2, 38**, a bias member (handle) biases the tubular member into the first (open) sleeve position (Col 8, Line 67, - Col 9, Line 7 and Col 22, Lines 9-13). **Regarding Claims 3, 39**, the biasing member is capable of being squeezed (Col 9, Lines 7-14) such that it would impart the claimed forces in the second position (closed). **Regarding Claims 45-46, 4-5, 7-8, 10**, the first compression element **550a** can emit ultrasonic energy and is considered an ultrasonic horn since it can do so (Col 2, Lines 62-65). **Regarding Claim 62**, an actuator comprises the handle **540** which is capable of applying force to a fastener positioned between the compressive elements and capable of securing a suture to the fastener by physical deformation or by employing the ultrasound energy as discussed above. **Regarding Claim 63**, it does not require much structure "to apply tension" to a suture since the suture can be tied around any portion of the sheath **512** such that the actuator would comprise the collar (as labeled **22** in the other embodiment) or loop **578** can be consider the second actuator

because it is capable looping through another suture such that elements **572A** and **572B** would comprise the actuator.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claim 44** are rejected under 35 U.S.C. 103(a) as being unpatentable over anticipated by **Yoon** in view of **Toy et al. ("Toy" US 5,772,672)** or **Stevens et al. ("Stevens" US 5,573,542)**.

**Yoon** discloses all of the claimed limitations except for the "collar including means for maintaining tension in the suture". From the claim language, it appears that the Applicant is invoking "means for" of 112 sixth paragraph. The "means for maintaining" appears to be directed to the "at least one notch **1212**" as depicted in Figs

52-53 and Paragraph 538. **Yoon** does disclose of a collar on the proximal end of the barrel **512** that has "longitudinal extending external grooves for facilitating grasping" (Col 5, Lines 48-51). **Yoon** does not disclose of a structure similar to the "at least one notch". However, **Toy** (Fig 2) and **Stevens** (Fig 1) both teach similar sheaths intended to be placed into the body comprising similar notches (finger loops) intended to be engaged by fingers. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the collar of the sheath of **Yoon** with the finger loops of **Toy** and **Stevens** in order to enhance the securement of the grasping which is desired (**Yoon** Col 5, Lines 48-51). In addition to facilitating manual grasping, the finger loops would be capable of maintaining tension to a suture if the suture was tied to it.

11. **Claims 52-53, 55** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Yoon** in view of **Bates et al.** ("**Bates**" **US 6,348,056**).

**Yoon** discloses all of the claimed limitations except for the proximal end of the elongated insulation sleeve including a channel for engaging a pin positioned on the second member, and wherein the channel and the pin cooperate to control a range of motion of the sleeve over the second member. However, **Bates** teaches of a similar medical delivery device comprising an instrument with an elongate body **40** which is retractable into a sleeve **12** wherein the retraction is controlled by a pin **18** of the elongate body being disposed in a groove **14** of the sleeve (Fig 11A-11B). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the second member and the sleeve of **Yoon** with the pin and groove as taught by **Bates**.



Doing so would facilitate the advancing and retracting of the instrument in and out of the sleeve (Col 10, Line 61, - Col 11, Line 2).

12. **Claim 57** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Yoon** in view of **Toy** or **Stevens** as applied to **claim 44** above, and further in view of **Bates**.

**Yoon** in view of **Toy** or **Stevens** discloses all of the claimed limitations except for the proximal end of the elongated insulation sleeve including a channel for engaging a pin positioned on the second member, and wherein the channel and the pin cooperate to control a range of motion of the sleeve over the second member. However, **Bates** teaches of a similar medical delivery device comprising an instrument with an elongate body **40** which is retractable into a sleeve **12** wherein the retraction is controlled by a pin **18** of the elongate body being disposed in a groove **14** of the sleeve (Fig 11A-11B). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the second member and the sleeve of **Yoon** in view of **Toy** or **Stevens** with the pin and groove as taught by **Bates**. Doing so would facilitate the advancing and retracting of the instrument in and out of the sleeve (Col 10, Line 61, - Col 11, Line 2).

### ***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Mashack whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Corrine McDermott, at (571) 272-4754.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

***If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to***

TC3700\_Workgroup\_D\_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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